

Approval Date: OCT 22 2004

**FREEDOM OF INFORMATION SUMMARY**  
**SUPPLEMENTAL ABBREVIATED NEW ANIMAL**  
**DRUG APPLICATION**

**ANADA 200-224**

**COMPONENT T-H and COMPONENT T-S**  
**(Trenbolone Acetate)**

**COMPONENT T-H with TYLAN and COMPONENT T-S with TYLAN**  
**(Trenbolone Acetate with Tylosin)**

**This supplement provides for addition to the labeling of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section and "Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established." immediately following the indications.**

**Sponsored by:**

**Ivy Laboratories**  
**Division of Ivy Animal Health, Inc.**  
**8857 Bond Street**  
**Overland Park, KS 66214**

## **FREEDOM OF INFORMATION SUMMARY**

**COMPONENT T-H and COMPONENT T-H with TYLAN  
Ear Implant for Feedlot Heifers**

**COMPONENT T-S and COMPONENT T-S with TYLAN  
Ear Implant for Feedlot Steers**

### ***1. GENERAL INFORMATION:***

- a. File Number: ANADA 200-224
- b. Sponsor: Ivy Laboratories  
Division of Ivy Animal Health, Inc.  
8857 Bond Street  
Overland Park, KS 66214  
Drug Labeler Code: 021641
- c. Established Names: Trenbolone Acetate  
Trenbolone Acetate with Tylosin
- d. Propriety Names: COMPONENT T-H, COMPONENT T-S,  
COMPONENT T-H with TYLAN, and  
COMPONENT T-S with TYLAN
- e. Dosage Form: Implantation (ear implant) as per 21 CFR 522.2476

f. How Supplied:

COMPONENT T-H: Each box contains 5 foil pouches each containing 1 cartridge belt with 20 cells. Each cartridge cell contains 1 implant dose. Each dose consists of trenbolone acetate 200 mg.

COMPONENT T-H with TYLAN: Each box contains 5 foil pouches each containing 1 cartridge belt with 20 cells. Each cartridge cell contains 1 implant dose. Each dose consists of trenbolone acetate 200 mg with 29 mg tylosin tartrate as a local antibacterial.

COMPONENT T-S: Each box contains 5 foil pouches each containing 1 cartridge belt with 20 cells. Each cartridge cell contains 1 implant dose. Each dose consists of trenbolone acetate 140 mg.

COMPONENT T-S with TYLAN: Each box contains 5 foil pouches each containing 1 cartridge belt with 20 cells. Each cartridge cell contains 1 implant dose. Each dose consists of trenbolone acetate 140 mg with 29 mg tylosin tartrate as a local antibacterial.

g. How Dispensed:

OTC

h. Amount of Active Ingredients:

COMPONENT T-H:  
200 mg trenbolone acetate.

COMPONENT T-H with TYLAN:  
200 mg trenbolone acetate.  
29 mg tylosin tartrate.

COMPONENT T-S:  
140 mg trenbolone acetate.

COMPONENT T-S:  
140 mg trenbolone acetate.  
29 mg tylosin tartrate.

i. Route of Administration:

Subcutaneous implantation on the posterior aspect of the middle one-third of the ear by means of an implant gun.

j. Species/Class:

Feedlot steers and heifers

- k. Recommended Dosage: COMPONENT T-H: One implant containing 200 mg trenbolone acetate.
- COMPONENT T-H with TYLAN: One implant containing 200 mg trenbolone acetate with 29 mg tylosin tartrate.
- COMPONENT T-S: One implant containing 140 mg trenbolone acetate.
- COMPONENT T-S with TYLAN: One implant containing 140 mg trenbolone acetate with 29 mg tylosin tartrate.
- l. Pharmacological Category: Steroid hormone, anti-bacterial
- m. Indications: COMPONENT T-H and COMPONENT T-H with TYLAN: For increased rate of weight gain and improved feed efficiency.
- COMPONENT T-S AND COMPONENT T-S with TYLAN: For improved feed efficiency.
- n. Effect of Supplement: This supplement provides for addition to the labeling of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section and "Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established." immediately following the label indications.

## **2. DRUG EFFECTIVENESS:**

No new effectiveness data are required for the approval of this supplement. The products' effectiveness has been established in the Freedom of Information (FOI) Summaries for the parent abbreviated new animal drug applications for COMPONENT T-H, COMPONENT T-H with TYLAN, COMPONENT T-S, and COMPONENT T-S with TYLAN (ANADA 200224).

## **3. TARGET ANIMAL SAFETY:**

No new target animal safety data are required for the approval of this supplement. The products' target animal safety has been established in the Freedom of Information (FOI)

Summaries for the parent abbreviated new animal drug applications for COMPONENT T-H, COMPONENT T-H with TYLAN, COMPONENT T-S, and COMPONENT T-S with TYLAN (ANADA 200224).

**4. HUMAN SAFETY:**

No new human food safety data are required for the approval of this supplement. The products' human food safety has been established in the Freedom of Information (FOI) Summaries for the parent abbreviated new animal drug applications for COMPONENT T-H, COMPONENT T-H with TYLAN, COMPONENT T-S, and COMPONENT T-S with TYLAN (ANADA 200224).

**5. AGENCY CONCLUSIONS:**

The information submitted in support of this ANADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations providing for the addition to the labeling of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section and "Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established." immediately following the indications. The labeling is modified to conform to agency policy (69 FR 135 pages 42443-42444 dated July 15, 2004, and 69 FR 68 page 18594 dated April 8, 2004.)

The Center for Veterinary Medicine has concluded that, for these products, adequate directions for use by the layperson have been provided and the products will have over-the-counter (OTC) status. Label directions are accompanied by pictorial diagrams and detailed instruction in plain language. The drugs are not controlled substances. The product status remains OTC. The labeling is adequate for the intended use and has sufficient warnings/statements to prevent illegal use in veal calves.

This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2)), this is a Category II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

COMPONENT T-H with TYLAN and COMPONENT T-S with TYLAN are under the following US patent number:

<u>U.S. Patent Number</u>	<u>Date of Expiration</u>
5,874,098	May 28, 2017

**6. ATTACHMENTS:**

Facsimile Labeling is attached as indicated below:

COMPONENT T-H Carton Label  
COMPONENT T-H Foil Pouch (Front)  
COMPONENT T-H Foil Pouch (Back)  
COMPONENT T-H Package Insert  
COMPONENT T-H with TYLAN Carton Label  
COMPONENT T-H with TYLAN Foil Pouch (Front)  
COMPONENT T-H with TYLAN Foil Pouch (Back)  
COMPONENT T-H with TYLAN Package Insert  
COMPONENT T-S Carton Label  
COMPONENT T-S Foil Pouch (Front)  
COMPONENT T-S Foil Pouch (Back)  
COMPONENT T-S Package Insert  
COMPONENT T-S with TYLAN Carton Label  
COMPONENT T-S with TYLAN Foil Pouch (Front)  
COMPONENT T-S with TYLAN Foil Pouch (Back)  
COMPONENT T-S with TYLAN Package Insert

**Storage Conditions:** Store in a refrigerator (2°-8°C; 36°-46°F) and protect from sunlight.  
Use before the expiration date.

**COMPONENT**  
BRAND IMPLANTS

**T-H**

trenbolone acetate 200 mg  
FOR FEEDLOT HEIFERS



COMPONENT T-H is a new, highly effective implant containing trenbolone acetate which increases rate of weight gain and improves feed efficiency in growing and finishing feedlot heifers. The product is to be used in feedlot heifers and young females of other beef breeds for increasing weight.

**Contents:** 5 (five) cartridges containing 100 mg each with 20 pellets. Each cartridge contains 1 implant dose. Each dose consists of 200 mg of trenbolone acetate.

**Dosage:** Administer 1 implant per animal. See package insert for detailed instructions. Do not use in heifers.

\* Estimated by Animal Health, Inc. (NADA 233423). Approved by FDA.

100 IMPLANTS



**WARNING:** Not to be used in animals intended for subsequent breeding, or in dairy animals. Implant one dose — 10 pellets (entire contents of one cartridge cell) — in the ear subcutaneously. Any other site of implantation is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.  
**A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.**

**RESTRICTED DRUG — USE ONLY AS DIRECTED (CALIFORNIA) — FOR USE IN ANIMALS ONLY —  
NOT FOR HUMAN USE — KEEP OUT OF REACH OF CHILDREN**

**Important**

Read the enclosed instruction brochure. Use as illustrated with a CAREFUL CLEAN TECHNIQUE. Never take short cuts at the expense of CLEANLINESS.

**Manufactured by a non-sterilizing process.**

COMPONENT is a registered trademark of Ivy Animal Health, Inc.  
Manufactured for VetLife by Ivy Laboratories • Overland Park, KS 66214, USA  
VetLife and Ivy Laboratories are divisions of Ivy Animal Health, Inc.

01 06 03 04

FOR FEEDLOT HEIFERS  
trenbolone acetate 200 mg  
**T-H**  
**COMPONENT**

3.125"



1/4" Seal Area

9.5"

**COMPONENT<sup>®</sup>**  
BRAND IMPLANTS

**T-H**

trenbolone acetate 200 mg

FOR FEEDLOT HEIFERS



**VetLife<sup>®</sup>**

TEAR HERE

COMPONENT T-H is a slow-release anabolic agent containing trenbolone acetate which increases rate of weight gain and improves feed efficiency in growing finishing feedlot heifers. This product is to be used in feedlot heifers only during approximately the last 60 days prior to slaughter.

Contains: One Cartridge Belt<sup>®</sup> of 20 implants sealed in a sanitary foil pouch.

Dosage: Administer 1 implant per animal. See package insert for detailed instructions. Do not use in veal calves.

Manufactured by a non-sterilizing process.

\* Patented by Ivy Animal Health, Inc.

ANADA 200-224, Approved by FDA  
One 20-Dose Cartridge Belt



18.3/5"

9.375"

TEAR HERE

**WARNING:** Not to be used in animals intended for subsequent breeding, or in dairy animals. Implant one dose — 10 pellets (entire contents of one cartridge cell) — in the ear subcutaneously. Any other site of implantation is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

**RESTRICTED DRUG — USE ONLY AS DIRECTED (CALIFORNIA) — FOR USE IN ANIMALS ONLY —  
NOT FOR HUMAN USE — KEEP OUT OF REACH OF CHILDREN**

**Important:** Read the enclosed instruction brochure. Use as illustrated with a CAREFUL CLEAN TECHNIQUE. Never take short cuts at the expense of GLEANLINESS.

**Storage Conditions:**

Store in a refrigerator (2°-8°C; 36°-46°F) and protect from sunlight.  
Use before the expiration date.

COMPONENT is a registered trademark of Ivy Animal Health, Inc.

Manufactured for VetLife by Ivy Laboratories • Overland Park, KS 66214, USA  
VetLife and Ivy Laboratories are divisions of Ivy Animal Health, Inc.  
01 06 02 05



EXP

LOT



GENESIS 1999032

**COMPONENT®**  
BRAND IMPLANTS

**T-H**

trenbolone acetate 200 mg

**VetLife**

FOR FEEDLOT HEIFERS

**20 dose CARTRIDGE BELT\***

For use with COMPONENT One Gun\*\*\*  
For Use In Animals Only

Each CARTRIDGE BELT holds 20 doses of COMPONENT® T-H Implants for feedlot heifers. Each dose of 10 pellets contains a total of 200 mg of trenbolone acetate. COMPONENT® T-H Implants are recommended for use in feedlot heifers for INCREASED RATE OF WEIGHT GAIN AND FEED EFFICIENCY.

**INDICATIONS FOR USE:** This product is a slow-release anabolic agent containing trenbolone acetate which increases rate of weight gain and improves feed efficiency in growing finishing feedlot heifers. This product is to be used in feedlot heifers only during approximately the last 63 days prior to slaughter. Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

**DOSAGE:** Administer 1 implant per animal according to the following instructions.

**GENERAL INSTRUCTIONS:** Study the instructions which should be followed carefully at all times, avoiding short cuts. Skin infection can be avoided by properly preparing implant site and implanter. During fly season use fly repellent on implant site. One designated team member should always do the implanting. Cleanliness of hands and instruments is important at all times.

**WARNING**

Not to be used in animals intended for subsequent breeding, or in dairy animals. Implant one dose — 10 pellets (entire contents of one cartridge cell) — in the ear subcutaneously. Any other site of implantation is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.

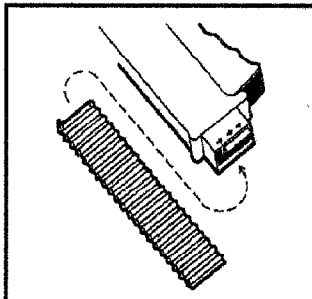
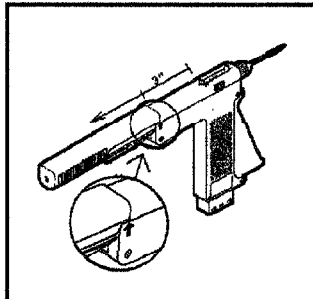
A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

**RESTRICTED DRUG — USE ONLY AS DIRECTED (CALIFORNIA) —  
FOR USE IN ANIMALS ONLY — NOT FOR HUMAN USE —  
KEEP OUT OF REACH OF CHILDREN**

**IMPLANTING INSTRUCTIONS:**

**Loading the Implanter**

Load the implanter following the instructions supplied with each implanter.



**Restrain the Animal**

Speed of implantation as well as safety of handlers is best achieved by restraining animal in a squeeze chute using head restraint. When implanting horned cattle, better control is obtained with additional use of nose tongs.

**Prepare the Implant Site**

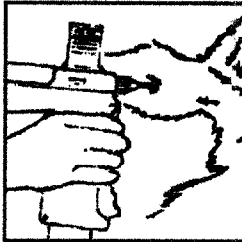
Scrub the back side of the ear (implant site) with a piece of clean absorbent cotton which has been soaked with topical germicidal solution. Follow manufacturer's directions on germicide for correct strength and preparation of solution. Avoid getting disinfectant in animal's eyes.

**Where to Implant**

The full contents of one cartridge cell should be implanted beneath the skin on the back side of the middle one-third of the ear as illustrated in the drawing. The implant must not be closer to the head than the edge of the auricular cartilage ring farthest from the head. The location for insertion of the needle is a point toward the tip of the ear and at least a needle length away from the intended deposition site. Avoid injuring the large arteries, veins and cartilage of the ear.

**Insert the Needle**

With one hand firmly grasp the ear. With the other hand insert needle point through the skin and ease forward on a lateral plane until the entire length of the needle is under the skin.

**Implant the Pellets**

After inserting the needle fully in the correct implant position, squeeze the trigger fully. As the needle is withdrawn from the ear, the controlled-pressure plunger action properly deposits the implant in the needle track. This procedure should prevent breakage or crushing of pellets if otherwise forced into contact with tough fibrous-tissue underlying the skin. The length and total contact area of a single dose are designed to permit absorption of the hormones after implantation to stimulate good weight gain. Broken or crushed pellets may interfere with rates of gain.

**Clean the Needle**

Clean the implanter needle with alcohol or a properly diluted germicidal solution prior to implanting the next animal.

**Storage Conditions**

Store in a refrigerator (2°-8°C; 36° to 46° F) and protect from sunlight. Use before the expiration date printed on foil pouch.

ANADA 200-224, Approved by FDA

**Manufactured by a non-sterilizing process.**

\*U.S. Patent No. 4,531,938

\*\*U.S. Patent Nos. 4,762,515 & 5,522,797 - Ivy Animal Health, Inc.

COMPONENT and COMPONENT One Gun are registered trademarks of Ivy Animal Health, Inc.

Manufactured for VetLife by Ivy Laboratories.

Overland Park, KS 66214, USA

VetLife and Ivy Laboratories are divisions of Ivy Animal Health, Inc.

#### Storage Conditions

Store in a refrigerator (2°-8°C; 36°-46°F) and protect from sunlight.  
Use before the expiration date.

## COMPONENT® T-H

BRAND IMPLANTS FOR FEEDLOT HEIFERS

trenbolone acetate 200 mg with 29 mg tylosin tartrate as a local antibacterial



COMPONENT T-H is a slow release system, a pellet containing testosterone and which produces a steady weight gain and improves feed efficiency in growing finishing feedlot heifers. This product is to be used in feedlot heifers only during approximately the last 60 days prior to slaughter.

Contents: 3 cartridges each containing 1 cartridge cell with 20 pellets. Each cartridge cell contains 1 implant dose. Each dose consists of 20 mg of trenbolone acetate with 29 mg of tylosin tartrate as a local antibacterial.

Dosage: Administer 1 implant per animal. See package insert for detailed instructions. Do not use in veal calves.

© Registered by Ivy Animal Health, Inc. CANADA 300-224. Approved by FDA.

100 IMPLANTS



Use With Gray  
Component  
One Gun® Only



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Use With Gray  
Component  
One Gun® Only

FOR FEEDLOT HEIFERS

trenbolone acetate 200 mg  
with 29 mg tylosin tartrate  
as a local antibacterial

COMPONENT® T-H

**WARNING: Not to be used in animals intended for subsequent breeding, or in dairy animals. Implant one dose — 11 pellets (entire contents of one cartridge cell) — in the ear subcutaneously. Any other site of implantation is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.**

**A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.**

**RESTRICTED DRUG — USE ONLY AS DIRECTED (CALIFORNIA) — FOR USE IN ANIMALS ONLY — NOT FOR HUMAN USE — KEEP OUT OF REACH OF CHILDREN**

**Important: Read the enclosed instruction brochure. Use as illustrated with a CAREFUL CLEAN TECHNIQUE. Never take short cuts at the expense of CLEANLINESS.**

**Manufactured by a non-sterilizing process.**

COMPONENT T-H with Tylan is covered by U.S. Patent No. 5,874,098  
COMPONENT is a registered trademark of Ivy Animal Health, Inc.  
Tylan is a registered trademark of Eli Lilly and Company.  
Manufactured for VetLife by Ivy Laboratories • Overland Park, KS 66214, USA  
VetLife and Ivy Laboratories are divisions of Ivy Animal Health, Inc.

01 26 03 02

3.125"



1/4" Seal Area

9.5"

# **COMPONENT<sup>®</sup> T-H**

BRAND IMPLANTS FOR FEEDLOT HEIFERS

trenbolone acetate 200 mg with 29 mg tylosin tartrate as a local antibacterial



**VetLife<sup>®</sup>**

TEAR HERE

COMPONENT<sup>®</sup> T-H is a slow-release anabolic agent containing trenbolone acetate which increases rate of weight gain and improves feed efficiency in growing finishing feedlot heifers. This product is to be used in feedlot heifers only during approximately the last 60 days prior to slaughter.

Contains: One Cartridge Belt<sup>®</sup> of 20 implants each inside 1 inch sanitary foil pouch. Each dose consists of 200 mg of trenbolone acetate with 29 mg tylosin tartrate as a local antibacterial.

Dosage: Administer 1 implant per animal. See package insert for detailed instructions. Do not use in beef calves.

Manufactured by a non-sterilizing process.

\* Patented by Ivax Animal Health, Inc. ANADA 200-224. Approved by FDA.



One 20-Dose Cartridge Belt

13.5/5"

9.375"

TEAR HERE

**WARNING:** Not to be used in animals intended for subsequent breeding, or in dairy animals. Implant one dose — 11 pellets (entire contents of one cartridge cell) — in the ear subcutaneously. Any other site of implantation is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.

**A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.**

**RESTRICTED DRUG — USE ONLY AS DIRECTED (CALIFORNIA) — FOR USE IN ANIMALS ONLY —  
NOT FOR HUMAN USE — KEEP OUT OF REACH OF CHILDREN**

**Important:** Read the enclosed instruction brochure. Use as illustrated with a CAREFUL CLEAN TECHNIQUE. Never take short cuts at the expense of CLEANLINESS.

**Storage Conditions:**

Store in a refrigerator (2°-8°C; 36°-46°F) and protect from sunlight.  
Use before the expiration date.

COMPONENT is a registered trademark of Ivy Animal Health, Inc.  
Tylan is a registered trademark of Eli Lilly and Company.  
Manufactured for **VetLife** by Ivy Laboratories • Overland Park, KS 66214, USA  
VetLife and Ivy Laboratories are divisions of Ivy Animal Health, Inc.

01 26 02 02

PURCHASE SEAL 20 IMPLANTS



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LOT

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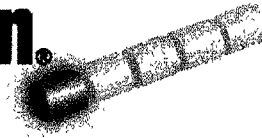
**COMPONENT®**  
BRAND IMPLANTS

**VetLife®**

# **T-H WITH Tylan®**

FOR FEEDLOT HEIFERS

trenbolone acetate 200 mg with  
29 mg tylosin tartrate as a local antibacterial



## **20 dose CARTRIDGE BELT\***

For use with the COMPONENT One Gun\*\*  
For Use in Animals Only

Each CARTRIDGE BELT holds 20 doses of COMPONENT® T-H Implants for feedlot heifers. Each dose of 11 pellets consists of 10 pellets containing a total of 200 mg of trenbolone acetate plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial. COMPONENT® T-H Implants are recommended for use in feedlot heifers for INCREASED RATE OF WEIGHT GAIN AND FEED EFFICIENCY.

**INDICATIONS FOR USE:** This product is a slow-release anabolic agent containing trenbolone acetate which increases rate of weight gain and improves feed efficiency in growing finishing feedlot heifers. This product is to be used in feedlot heifers only during approximately the last 63 days prior to slaughter. Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

**DOSAGE:** Administer 1 implant per animal according to the following instructions.

**GENERAL INSTRUCTIONS:** Study the instructions which should be followed carefully at all times, avoiding short cuts. Skin infection can be avoided by properly preparing implant site and implanter. During fly season use fly repellent on implant site. One designated team member should always do the implanting. Cleanliness of hands and instruments is important at all times.

### **WARNING**

Not to be used in animals intended for subsequent breeding, or in dairy animals. Implant one dose — 11 pellets (entire contents of one cartridge cell) — in the ear subcutaneously. Any other site of implantation is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.

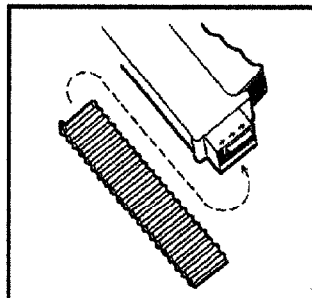
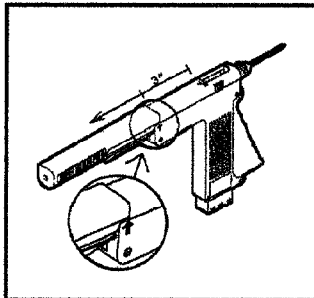
A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

**RESTRICTED DRUG — USE ONLY AS DIRECTED (CALIFORNIA) —  
FOR USE IN ANIMALS ONLY — NOT FOR HUMAN USE —  
KEEP OUT OF REACH OF CHILDREN**

### **IMPLANTING INSTRUCTIONS:**

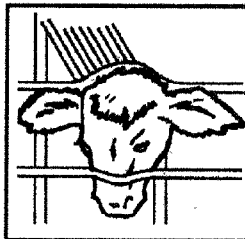
#### **Loading the Implanter**

Load the implanter following the instructions supplied with each implanter.



**Restrain the Animal**

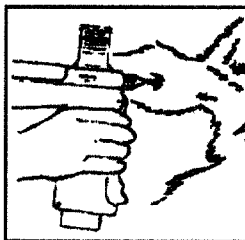
Speed of implantation as well as safety of handlers is best achieved by restraining animal in a squeeze chute using head restraint. When implanting horned cattle, better control is obtained with additional use of nose tongs.

**Prepare the Implant Site**

Scrub the back side of the ear (implant site) with a piece of clean absorbent cotton which has been soaked with topical germicidal solution. Follow manufacturer's directions on germicide for correct strength and preparation of solution. Avoid getting disinfectant in animal's eyes.

**Where to Implant**

The full contents of one cartridge cell should be implanted beneath the skin on the back side of the middle one-third of the ear as illustrated in the drawing. The implant must not be closer to the head than the edge of the auricular cartilage ring farthest from the head. The location for insertion of the needle is a point toward the tip of the ear and at least a needle length away from the intended deposition site. Avoid injuring the large arteries, veins and cartilage of the ear.

**Insert the Needle**

With one hand firmly grasp the ear. With the other hand insert needle point through the skin and ease forward on a lateral plane until the entire length of the needle is under the skin.

**Implant the Pellets**

After inserting the needle fully in the correct implant position, squeeze the trigger fully. As the needle is withdrawn from the ear, the controlled-pressure plunger action properly deposits the implant in the needle track. This procedure should prevent breakage or crushing of pellets if otherwise forced into contact with tough fibrous-tissue underlying the skin. The length and total contact area of a single dose are designed to permit absorption of the hormones after implantation to stimulate good weight gain. Broken or crushed pellets may interfere with rates of gain.

**Clean the Needle**

Clean the implanter needle with alcohol or a properly diluted germicidal solution prior to implanting the next animal.

**Storage Conditions**

Store in a refrigerator (2°-8°C; 36° to 46° F) and protect from sunlight. Use before the expiration date printed on foil pouch.

ANADA 200-224, Approved by FDA

**Manufactured by a non-sterilizing process.**

\*U.S. Patent No. 4,531,938

\*\*U.S. Patent Nos. 4,762,515 & 5,522,797 – Ivy Animal Health, Inc.  
COMPONENT T-H with Tylan is covered by U.S. Patent No. 5,874,098

COMPONENT and COMPONENT One Gun are registered trademarks of Ivy Animal Health, Inc.

Tylan is a registered trademark of Eli Lilly and Company.

Manufactured for VetLife by Ivy Laboratories.

Overland Park, KS 66214, USA

VetLife and Ivy Laboratories are divisions of Ivy Animal Health, Inc.



**Storage Conditions:** Store in a refrigerator (2°-8°C; 36°-46°F) and protect from sunlight.  
Use before the expiration date.

# COMPONENT® T-S

BRAND IMPLANTS FOR FEEDLOT STEERS

trenbolone acetate 140 mg



COMPONENT T-S is a slow-release anabolic agent containing trenbolone acetate for increased feed efficiency and growth in young feedlot steers. For continued effect, these implants should be replaced once after 90 days.

**Contents:** 510 cartridges each containing 7 cartridge cells with 7 pellets. Each cartridge cell contains 1 pellet of trenbolone acetate 140 mg.

**Dosage:** Administer 1 implant per animal. See packaging for full detailed instructions. Do not use in young calves.

Patented by Ivy Animal Health, Inc. CANADA 200-224. Approved by FDA.

100 IMPLANTS



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**WARNING:** Not to be used in animals intended for subsequent breeding, or in dairy animals. Implant one dose — 7 pellets (entire contents of one cartridge cell) — in the ear subcutaneously. Any other site of implantation is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.

**A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.**

**RESTRICTED DRUG — USE ONLY AS DIRECTED (CALIFORNIA) — FOR USE IN ANIMALS ONLY —  
NOT FOR HUMAN USE — KEEP OUT OF REACH OF CHILDREN**

**Important:** Read the enclosed instruction brochure. Use as illustrated with a CAREFUL CLEAN TECHNIQUE.  
Never take short cuts at the expense of CLEANLINESS.

**Manufactured by a non-sterilizing process.**

COMPONENT T-S with Tylan is covered by U.S. Patent No. 5,874,098  
COMPONENT is a registered trademark of Ivy Animal Health, Inc.  
Manufactured for VetLife by Ivy Laboratories • Overland Park, KS 66214, USA  
VetLife and Ivy Laboratories are divisions of Ivy Animal Health, Inc.

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FOR FEEDLOT STEERS

trenbolone acetate 140 mg

**COMPONENT® T-S**

3.125"

1/4" Seal Area

**COMPONENT**  
BRAND IMPLANTS

**T-S**

trenbolone acetate 140 mg

FOR FEEDLOT STEERS



TEAR HERE

COMPONENT T-S is a slow release anabolic agent containing trenbolone acetate which improves feed efficiency in growing finishing feedlot steers. For continued effectiveness this product should be reimplanted once after 63 days.

Contains: One Cartridge Belt of 20 implants sealed in a sanitary foil pouch.

Dosage: Administer 1 implant per animal. See package insert for detailed instructions. Do not use in heifer calves.

Manufactured by a non-sterilizing process.

Patented by Ivy Animal Health, Inc.

ANADA 200-224, Approved by FDA

One 20-Dose Cartridge Belt

9.5"

18.875"

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**WARNING**  
contents

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18.875"

9.375"

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**WARNING: Not to be used in animals intended for subsequent breeding, or in dairy animals.** Implant one dose — 7 pellets (entire contents of one cartridge cell) — in the ear subcutaneously. Any other site of implantation is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.

**A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.**

**RESTRICTED DRUG — USE ONLY AS DIRECTED (CALIFORNIA) — FOR USE IN ANIMALS ONLY —  
NOT FOR HUMAN USE — KEEP OUT OF REACH OF CHILDREN**

**Important:** Read the enclosed instruction brochure. Use as illustrated with a CAREFUL CLEAN TECHNIQUE. Never take short cuts at the expense of CLEANLINESS.

**Storage Conditions:** Store in a refrigerator (2°-8°C; 36°-46°F) and protect from sunlight. Use before the expiration date.

COMPONENT is a registered trademark of Ivy Animal Health, Inc.

Manufactured for **VetLife** by Ivy Laboratories • Overland Park, KS 66214, USA  
VetLife and Ivy Laboratories are divisions of Ivy Animal Health, Inc.

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PURCHASE SEAL  
20 IMPLANTS



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**COMPONENT®**  
BRAND IMPLANTS

**T-S**

trenbolone acetate 140 mg

**VetLife®**  
FOR FEEDLOT STEERS

### 20 dose CARTRIDGE BELT\*

For use with the COMPONENT One Gun\*\*  
For Use In Animals Only

Each CARTRIDGE BELT holds 20 doses of COMPONENT® T-S Implants for feedlot steers. Each dose of 7 pellets contains a total of 140 mg of trenbolone acetate. COMPONENT® T-S Implants are recommended for use in feedlot steers for IMPROVED FEED EFFICIENCY.

**INDICATIONS FOR USE:** This product is a slow-release anabolic agent containing trenbolone acetate, which improves feed efficiency in growing finishing feedlot steers. For continued effectiveness this product should be reimplanted once after 63 days. Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

**DOSAGE:** Administer 1 implant per animal according to the following instructions.

**GENERAL INSTRUCTIONS:** Study the instructions which should be followed carefully at all times, avoiding short cuts. Skin infection can be avoided by properly preparing implant site and implanter. During fly season use fly repellent on implant site. One designated team member should always do the implanting. Cleanliness of hands and instruments is important at all times.

#### WARNING

Not to be used in animals intended for subsequent breeding, or in dairy animals. Implant one dose — 7 pellets (entire contents of one cartridge cell) — in the ear subcutaneously. Any other site of implantation is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.

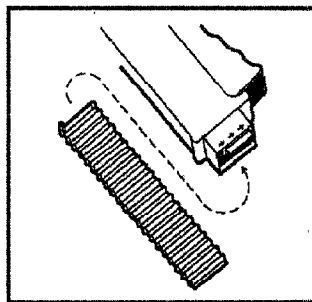
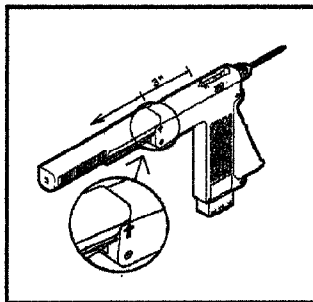
A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

**RESTRICTED DRUG — USE ONLY AS DIRECTED (CALIFORNIA) —  
FOR USE IN ANIMALS ONLY — NOT FOR HUMAN USE —  
KEEP OUT OF REACH OF CHILDREN**

#### IMPLANTING INSTRUCTIONS:

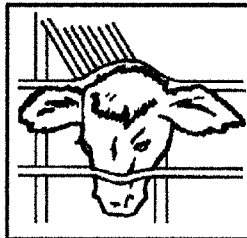
##### Loading the Implanter

Load the implanter following the instructions supplied with each implanter.



**Restrain the Animal**

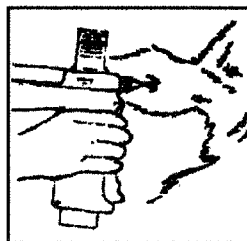
Speed of implantation as well as safety of handlers is best achieved by restraining animal in a squeeze chute using head restraint. When implanting horned cattle, better control is obtained with additional use of nose tongs.

**Prepare the Implant Site**

Scrub the back side of the ear (implant site) with a piece of clean absorbent cotton which has been soaked with topical germicidal solution. Follow manufacturer's directions on germicide for correct strength and preparation of solution. Avoid getting disinfectant in animal's eyes.

**Where to Implant**

The full contents of one cartridge cell should be implanted beneath the skin on the back side of the middle one-third of the ear as illustrated in the drawing. The implant must not be closer to the head than the edge of the auricular cartilage ring farthest from the head. The location for insertion of the needle is a point toward the tip of the ear and at least a needle length away from the intended deposition site. Avoid injuring the large arteries, veins and cartilage of the ear.

**Insert the Needle**

With one hand firmly grasp the ear. With the other hand insert needle point through the skin and ease forward on a lateral plane until the entire length of the needle is under the skin.

**Implant the Pellets**

After inserting the needle fully in the correct implant position, squeeze the trigger fully. As the needle is withdrawn from the ear, the controlled-pressure plunger action properly deposits the implant in the needle track. This procedure should prevent breakage or crushing of pellets if otherwise forced into contact with tough fibrous-tissue underlying the skin. The length and total contact area of a single dose are designed to permit absorption of the hormones after implantation to stimulate good weight gain. Broken or crushed pellets may interfere with rates of gain.

**Clean the Needle**

Clean the implanter needle with alcohol or a properly diluted germicidal solution prior to implanting the next animal.

**Storage Conditions**

Store in a refrigerator (2°-8°C; 36° to 46° F) and protect from sunlight. Use before the expiration date printed on foil pouch.

ANADA 200-224, Approved by FDA

**Manufactured by a non-sterilizing process.**

\*U.S. Patent No. 4,531,988

\*\*U.S. Patent Nos. 4,762,515 & 5,522,797 - Ivy Animal Health, Inc.

COMPONENT T-S with Tylan is covered by U.S. Patent No. 5,874,098

COMPONENT and COMPONENT One Gun are registered trademarks of Ivy Animal Health, Inc.

Manufactured for VetLife by Ivy Laboratories.

Overland Park, KS 66214, USA

VetLife and Ivy Laboratories are divisions of Ivy Animal Health, Inc.

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**Storage Conditions:** Store in a refrigerator (2°-8°C; 36°-46°F) and protect from sunlight.  
Use before the expiration date.

# COMPONENT® T-S

BRAND IMPLANTS FOR FEEDLOT STEERS

trenbolone acetate 140 mg with 29 mg tylosin tartrate as a local antibacterial



COMPONENT T-S is a slow release steroid implant containing trenbolone acetate for improved feed efficiency in growing finishing feedlot steers. The controlled effectiveness of this product should be maintained once after 30 days.

**Contents:** 8 foil ampoules each containing 10 cartridge cells with 20 pellets. Each cartridge cell contains 1 implant dose. Each dose consists of 140 mg of trenbolone acetate with 29 mg tylosin tartrate as a local antibacterial.

**Dosage:** Administer 1 implant per animal. See package insert for detailed instructions. Do not use in veal calves.

Patented by Ivy Animal Health, Inc. ANADA 280-224. Approved by FDA.

100 IMPLANTS



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**WARNING: Not to be used in animals intended for subsequent breeding, or in dairy animals. Implant one dose — 8 pellets (entire contents of one cartridge cell) — in the ear subcutaneously. Any other site of implantation is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.**

**A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.**

**RESTRICTED DRUG — USE ONLY AS DIRECTED (CALIFORNIA) — FOR USE IN ANIMALS ONLY — NOT FOR HUMAN USE — KEEP OUT OF REACH OF CHILDREN**

**Important:** Read the enclosed instruction brochure. Use as illustrated with a CAREFUL CLEAN TECHNIQUE.

Never take short cuts at the expense of CLEANLINESS.

**Manufactured by a non-sterilizing process.**

COMPONENT T-S with Tylosin is covered by U.S. Patent No. 5,874,088  
COMPONENT is a registered trademark of Ivy Animal Health, Inc.  
Tylosin is a registered trademark of Eli Lilly and Company.  
Manufactured for VetLife by Ivy Laboratories • Overland Park, KS 66214, USA  
VetLife and Ivy Laboratories are divisions of Ivy Animal Health, Inc.

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Use With Gray  
Component  
One Gun® Only

FOR FEEDLOT STEERS  
as a local antibacterial

trenbolone acetate 140 mg  
with 29 mg tylosin tartrate  
T-S  
COMPONENT®

3.125"

9.5"

## **COMPONENT<sup>®</sup> T-S**

BRAND IMPLANTS

FOR FEEDLOT STEERS

trenbolone acetate 140 mg with 29 mg tylosin tartrate as a local antibacterial



**VetLife<sup>®</sup>**

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COMPONENT<sup>®</sup> T-S is a slow release anabolic agent containing trenbolone acetate, which improves feed efficiency in growing finishing feedlot steers. For continued effectiveness this product should be reimplanted once after 63 days.

**Contains:** One Cartridge Belt<sup>®</sup> of 20 implants each sealed in a sanitary foil pouch. Each dose consists of 140 mg of trenbolone acetate with 29 mg tylosin tartrate as a local antibacterial.

**Dosage:** Administer 1 implant per animal. See package insert for detailed instructions. Do not use in veal calves.

**Manufactured by a non-sterilizing process.**

Patented by Wyeth Animal Health, Inc. ANADA 200 224. Approved by FDA.



One 20-Dose Cartridge Belt

1/4" Seal Area

18.875"

9.375"

TEAR HERE

**WARNING:** Not to be used in animals intended for subsequent breeding, or in dairy animals. Implant one dose — 8 pellets (entire contents of one cartridge cell) — in the ear subcutaneously. Any other site of implantation is in violation of Federal Law. DO NOT attempt to salvage implantation site for animal feed or human food.

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

**RESTRICTED DRUG — USE ONLY AS DIRECTED (CALIFORNIA) — FOR USE IN ANIMALS ONLY —  
NOT FOR HUMAN USE — KEEP OUT OF REACH OF CHILDREN**

**Important:** Read the enclosed instruction brochure. Use as illustrated with a CAREFUL CLEAN TECHNIQUE. Never take short cuts at the expense of CLEANLINESS.

**Storage Conditions:** Store in a refrigerator (2°-8°C; 36°-46°F) and protect from sunlight. Use before the expiration date.

COMPONENT is a registered trademark of Ivy Animal Health, Inc.

Tylan is a registered trademark of Eli Lilly and Company.

Manufactured for VetLife by Ivy Laboratories • Overland Park, KS 66214, USA

VetLife and Ivy Laboratories are divisions of Ivy Animal Health, Inc.

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PURCHASE SEAL 20 IMPLANTS



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**COMPONENT®**  
BRAND IMPLANTS

**VetLife**

# T-S WITH Tylan.

FOR FEEDLOT STEERS

trenbolone acetate 140 mg with  
29 mg tylosin tartrate as a local antibacterial



## 20 dose CARTRIDGE BELT\*

For use with the COMPONENT One Gun\*\*  
For Use In Animals Only

Each CARTRIDGE BELT holds 20 doses of COMPONENT® T-S Implants for feedlot steers. Each dose of 8 pellets consists of 7 pellets containing a total of 140 mg of trenbolone acetate USP plus 1 pellet containing 29 mg tylosin tartrate as a local antibacterial. COMPONENT® T-S Implants are recommended for use in feedlot steers for IMPROVED FEED EFFICIENCY.

**INDICATIONS FOR USE:** This product is a slow-release anabolic agent containing trenbolone acetate which improves feed efficiency in growing finishing feedlot steers. For continued effectiveness this product should be reimplanted once after 63 days. Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.

**DOSAGE:** Administer 1 implant per animal according to the following instructions.

**GENERAL INSTRUCTIONS:** Study the instructions which should be followed carefully at all times, avoiding short cuts. Skin infection can be avoided by properly preparing implant site and implanter. During fly season use fly repellent on implant site. One designated team member should always do the implanting. Cleanliness of hands and instruments is important at all times.

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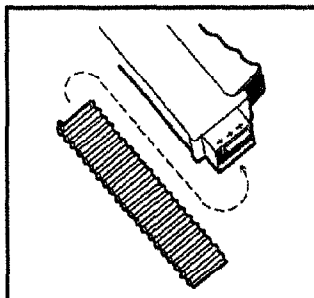
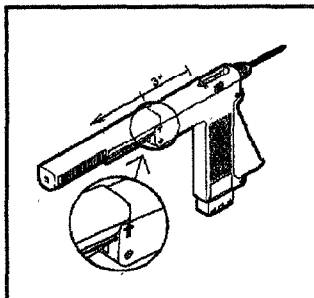
A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

**RESTRICTED DRUG — USE ONLY AS DIRECTED (CALIFORNIA) —  
FOR USE IN ANIMALS ONLY — NOT FOR HUMAN USE —  
KEEP OUT OF REACH OF CHILDREN**

### IMPLANTING INSTRUCTIONS:

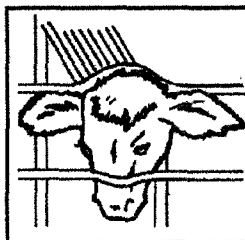
#### Loading the Implanter

Load the implanter following the instructions supplied with each implanter.



**Restrain the Animal**

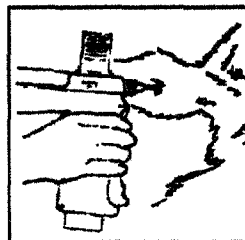
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**Implant the Pellets**

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**Storage Conditions**

Store in a refrigerator (2°-8°C; 36° to 46° F) and protect from sunlight. Use before the expiration date printed on foil pouch.

ANADA 200-224, Approved by FDA

Manufactured by a non-sterilizing process.

\*U.S. Patent No. 4,531,938

\*\*U.S. Patent Nos. 4,762,515 & 5,522,797 - Ivy Animal Health, Inc.

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